September 29, 2000

Avada

Audiology & Hearing Care

8531

Administrative Offices
Avada Building • 1022 N. Main St. • Butler, PA 16001 • 724-282-8491

Honorable Donna Shalala Secretary of Health and Human Services 200 Independence Avenue, S.W. Room 615F Washington, D.C. 20201

Dear Secretary Shalala:

As a hearing instrument specialist and hearing health care provider for the past 15 years, I write with respect to hearing aids. As the AARP has confirmed, hearing aids are highly effective but dramatically underutilized medical devices.

I am very concerned that the Food and Drug Administration (FDA) has reportedly sent you a proposal for revising the current regulations governing the dispensing of hearing aids in this country that would dramatically increase the cost of hearing health care services and restrict access to hearing health care providers. Please stop and carefully consider the impact that this proposed rule will have on the nation's hearing impaired and on the nation's small business hearing aid specialists. In particular, please ensure that any proposed rule meets the obligations of the Small Business Regulatory Fairness Act.

Hearing impairment is a major health care concern. Please don't let the FDA put forth their proposed rule that would impede access to needed hearing health care services for millions of Americans.

Very truly yours,

Gary L. Roberts, BC-HIS glrob@bellatlantic.net

93N 0372

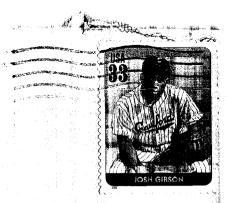
C4634

<sup>•</sup> Diagnostic Hearing Evaluation • Aural Rehabilitation • Hearing Instrument Fitting •

<sup>•</sup> Industrial Hearing Examination • Tinnitus Management • Cerumen Management •

Gary Roberts 2715 20th St. Ext. Beaver Falls, Pa 15010





Honorable Donna Shalala Secretary of Health and Human Services 200 Independence Avenue, S.W. Room 615F Washington, DC 20201

labillarabillaradibleh